**IN THE U.S. DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF OHIO**
**WESTERN DIVISION**

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| **BROOK REYNOLDS, ROBERT REYNOLDS, JULIE REYNOLDS, JENNI AKINS, MAJOR AKINS, RUBY GINNS** | CASE NO.: 3:15-cv-397<br><br>JUDGE: _____ |
| Plaintiffs,<br><br>v.<br><br>**MERCK SHARP & DOHME CORP., MERCK & CO., INC., SCHERING-PLOUGH CORPORATION, N.V. ORGANON, ORGANON USA, INC. AND JOHN DOE ENTITIES [Real Names and Addresses Unknown]**<br><br>Defendants.<br>_____/ | **COMPLAINT WITH JURY DEMAND ENDORSED HEREON**<br><br>Pamela A. Borgess (0072789)<br>Carasusana B. Wall (0090234)<br>James G. O'Brien (0088460)<br>ZOLL, KRANZ & BORGESS, LLC<br>6620 W. Central Ave., Suite 100<br>Toledo, OH 43617<br>Tel. (419) 841-9623<br>Fax: (419) 841-9719<br>Email: pamela@zkblaw.com<br>cara@zkblaw.com<br>jim@zkblaw.com<br><br>*Counsel for Plaintiffs* |

Now come Plaintiffs Brook Reynolds, Julie Reynolds, Robert Reynolds, Jenni Akins, Major Akins and Ruby Ginns, by and through the undersigned counsel, and hereby bring this Complaint against Defendants Merck Sharp and Dohme, Corp., Merck & Co., Inc., Schering-Plough Corporation, N.V. Organon, Organon USA, Inc., and the Doe Defendants.

## NATURE OF THE ACTION

1. This is an action brought by Plaintiffs for damages suffered as a direct and proximate result of Plaintiffs' use of the defective and unreasonably dangerous pharmaceutical product, Implanon® (etonogestrel implant). At all times relevant hereto, Implanon® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants.

2. As a result of their use of Implanon®, Plaintiffs suffered injuries including spontaneous migration of the implants beyond the implant site, inability to locate the implants, unsuccessful and invasive attempts at implant removal, and inability to remove the lost implants. As a result of their lost, irretrievable and irreversible implants, Plaintiffs also each suffer the threat of future infertility, ectopic pregnancy, the inability to stop a drug-related adverse event, neural and vascular damage and other potential injuries.

## THE PARTIES

3. Plaintiffs Brook Reynolds, Julie Reynolds and Robert Reynolds are citizens of Graytown, Ohio.

4. Plaintiffs Robert and Julie Reynolds are the parents of Plaintiff Brook Reynolds, an adult, who incurred damages, including medical and other economic expenses as a result of the injuries to their daughter.

5. Plaintiff Ruby Ginns is a citizen of Indianapolis, Indiana.

6. Plaintiffs Jenni and Major Akins are citizens of Florence, Alabama.

7. Plaintiff Major Akins is the spouse of Plaintiff Jenni Akins.

8. Defendant N.V. Organon is a foreign corporation and citizen with a principal place of business at Molenstraat 110, 5342 OCC Oss in the Netherlands.

9. Upon information and belief, Defendant N.V. Organon manufactured Implanon® for Defendant Organon USA, Inc.

10. At all relevant times, Defendant N.V. Organon has transacted and conducted business in the States of Ohio, Indiana and Alabama, and derived substantial revenue from interstate commerce.

11. Defendant Organon USA, Inc. is a New Jersey corporation with its principal place of business at 56 Livingston Ave., Roseland, New Jersey 0768. Defendant Organon USA, Inc. is therefore a citizen of New Jersey.

12. Defendant Organon USA, Inc. packages, markets and distributes products manufactured by N.V. Organon.

13. At all relevant times, Defendant Organon USA, Inc. was engaged in the distribution, selling, marketing and/or introduction into interstate commerce, either directly or indirectly through third parties or related entities, of the etonogestrel implant, Implanon®.

14. At all relevant times, Defendant Organon USA, Inc. has transacted and conducted business in the States of Ohio, Indiana and Alabama, and derived substantial revenue from interstate commerce.

15. Defendant Organon USA, Inc. is the holder of the approved New Drug Application ("NDA") for Implanon®.

16. Defendant Schering-Plough Corporation is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 0733. Defendant Schering-Plough Corporation is therefore a citizen of New Jersey.

17. Upon information and belief, Defendant Schering-Plough Corporation acquired Organon BioSciences NV in November 2007 and assumed all liabilities attendant thereto, including the liabilities of Defendant Organon USA, Inc.

18. Hereinafter, Defendants N.V. Organon, Organon USA, Inc., and Schering-Plough Corporation will be collectively referred to as "Organon Defendants."

19. Defendant Merck & Co., Inc. is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Defendant Merck & Co., Inc. is therefore a citizen of New Jersey.

20. Defendant Merck Sharp & Dohme Corp. is a New Jersey corporation with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey, 08889. Defendant Merck Sharp & Dohme Corp. is therefore a citizen of New Jersey.

21. Upon information and belief, in November 2009, Defendant Merck & Co., Inc. completed a merger with Defendant Schering-Plough Corporation, which included Organon and the liabilities and assets associated with Implanon®.

22. Upon information and belief, Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. have continued the business and operation of Schering-Plough Corporation and the "Organon Defendants" named herein.

23. Defendants Merck Sharp & Dohme Corp. and Merck & Co., Inc. are and were at all relevant times engaged in the business of researching, developing, designing, manufacturing, distributing, supplying, selling, marketing and/or introducing into

interstate commerce, either directly or indirectly through third parties or related entities, its products, including the etonogestrel implant, Implanon®.

24. At all relevant times Defendant Merck & Co. Inc. and Defendant Merck Sharp & Dohme Corp. have transacted and conducted business in the States of Ohio, Indiana and Alabama, and derived substantial revenue from interstate commerce.

25. Upon information and belief, Defendants John Doe Entities 1 through 10 (the "Doe Defendants") are corporations or other business entities, the names and addresses of which are unknown, who were involved in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, promotion and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the etonogestrel implant, Implanon®.

26. In the interest of clarity, this Complaint refers to Defendant N.V. Organon, Defendant Organon USA, Inc., Defendant Schering-Plough Corp., Defendant Merck & Co., Inc., and Merck Sharp & Dohme Corp. and Doe Defendants as "Defendants."

27. Defendants do business in Ohio, Indiana and Alabama, where Plaintiffs were implanted with the etogenstrel implant, Implanon® through the sales of Implanon® and other prescription drugs and products in those states.

28. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, promoting and/or introducing into interstate commerce, either directly or indirectly through third parties, subsidiaries or related entities, the etonogestrel implant, Implanon®.

29. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational

units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

30. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

## JURISDICTION AND VENUE

31. This Court has jurisdiction over this action pursuant to 28 U.S.C.A. § 1332, as there is complete diversity of citizenship between Plaintiffs and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

32. Venue is proper in the Northern District of Ohio, Western Division pursuant to 28 U.S.C.A. § 1391, as the sale and promotion of Implanon®, prescription and implantation of Implanon®, and resulting injuries occurred within this district.

33. The Court has personal jurisdiction over Defendants consistent with the Ohio and United States Constitutions and pursuant to Ohio R. C. § 2307.382(4) because Defendants caused tortious injury in Ohio by an act or omission outside Ohio by virtue of Defendants' regularly conducted business in Ohio from which they respectively derive substantial revenue. Defendants do substantial business in the State of Ohio and within the Northern District of Ohio, advertise in this district, and receive substantial compensation and profits from sales of Implanon® within this District.

34. Defendants expected or should have expected that their business activities could or would have consequences within the States of Ohio, Indiana and Alabama, as well as throughout the United States.

35. Joinder of the Indiana and Alabama claims is made pursuant to Fed. R. Civ. Proc. 20(a).

## FACTS
## Implanon® Background

36. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

37. Implanon® is a single rod implant containing etonogestrel, a synthetic progestin, for subdermal use. The implant, similar in size to a matchstick, is 4 cm in length with a diameter of 2 mm. Implanon® releases a progestin hormone indicated for use by women to prevent pregnancy.

38. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Implanon® in July 2006.

39. Implanon® includes an applicator that allows the health practitioner to insert the Implanon® into a patient's arm. Post-insertion palpation confirms placement in accordance with Defendants' instructions.

40. Implanon® is intended to be removed by the end of the third year after implantation.

41. Defendants directly marketed Implanon® to women and their physicians as a safe and effective contraceptive option. Defendants also represented and marketed Implanon® directly to women and their physicians as "reversible" and able to be

removed whenever the patient "change[s] [her] mind." The representations by Defendants were in fact false, misleading, and inaccurate, as Implanon® is not safe and is defective as described herein.

42. Defendants' claims regarding the safety and efficacy of Implanon® failed to provide an accurate and/or adequate warning of Implanon®'s risks to Plaintiffs and their healthcare providers, despite Defendants awareness of these risks.

43. Defendants knew or should have known that Implanon® had a potential to, could, and would cause severe injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

44. Defendants knew or should have known about the propensity of Implanon® to cause harm, including the risk of spontaneous migration after insertion in accordance with Defendants' instructions. Defendants also knew or should have known that since Implanon® is not radiopaque there may be no way to locate a lost implant with imaging technologies. Defendants, however, failed to provide accurate and/or adequate warning of these known risks.

45. Instead, Defendants only warned of migration during and from improper insertion, stating that "Deep insertions may lead to difficult or impossible removals" and that "too deep insertions have been associated with paresthesia (due to neural damage**),** migration of the implant (due to intramuscular or fascial insertion), and in rare cases with intravascular insertion." Defendants did not provide accurate and/or adequate warnings of the risk of later, spontaneous migration after insertion in accordance with Defendants' instructions. Defendants also did not provide accurate and/or adequate warning that the

Implanon® may become lost in the body and that its non-radiopaque design may entirely prevent imaging technologies from locating and retrieving a lost Implanon®.

46. Defendants knew or should have known that Implanon®, including its insertion applicator, was defective in its design, testing, manufacture, insufficient warnings, and/or failure to conform to Defendants' representations.

47. Defendants knew that feasible alternative designs existed that were capable of preventing lost, irretrievable implants, including the addition of barium sulphate to the implant to make it radiopaque and/or applicator changes, but Defendants still continued to heavily promote, sell, advertise and market Implanon® despite their knowledge.

48. In representations to Plaintiffs, their healthcare providers, and/or the public, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That Implanon® inserted in accordance with Defendants' instruction had the propensity to later, spontaneously migrate;

b. That Implanon® had the propensity to become lost in a woman's body and that its non-radiopaque design may entirely prevent imaging technologies from locating and retrieving the lost Implanon®;

c. Plaintiffs were put at risk of experiencing serious and dangerous side effects including, but not limited to, spontaneous migration after insertion in accordance with Defendants' instructions, a lost and irretrievable implant, inability to stop drug-related adverse events or complication, neural damage, vascular damage, ectopic pregnancy, fertility issues, as well as other severe and personal injuries, physical pain, and mental anguish; and/or

d. That Implanon®, including its insertion applicator was designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

49. Defendants were under a duty to disclose to Plaintiffs and their physicians, healthcare providers and/or the public the defective nature of Implanon®.

50. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to person who used Implanon®, including Plaintiffs.

51. Upon information and belief, Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of Implanon® with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, would rely on such in selecting Implanon® as a contraceptive.

52. Upon information and belief, Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Implanon® in their labeling, advertising, product inserts, promotional material or other marketing efforts.

53. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, their sales representative, employees, distributors, agents and/or detail persons.

54. Defendants knew that Plaintiffs, their healthcare providers and the public had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Implanon®, as set forth herein.

55. Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, about the potential risks and serious side effects associated with the use of Implanon® in a timely manner, yet they failed to provide such warning.

56. While still continuing to aggressively promote and market the non-radiopaque Implanon® as safe and "reversible" despite their knowledge of the serious risk of lost, irretrievable and irreversible implants, Defendants developed the bio-equivalent Nexplanon® (marketed in some countries as Implanon® NXT) to address Implanon®'s defects and ultimately, replace it. Although bio-equivalent, Nexplanon® is radiopaque so that it can be found using imagining technologies and has a re-designed insertion applicator intended to insure an optimal subdermal location.

57. On July 29, 2009, Defendants submitted a Supplemental New Drug Application to the FDA for the Nexplanon® etonogestrel implant that relied upon the Implanon®'s New Drug Application #021529.

58. The FDA approved Nexplanon® on May 13, 2011.

59. Upon information and belief, Implanon® is no longer marketed in the United States.

**FACTS REGARDING PLAINTIFF BROOK REYNOLDS**

60. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

61. Plaintiff Brook Reynolds was prescribed Implanon® by her health care provider.

62. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants as described herein to purchase Implanon® to her detriment.

63. On May 14, 2012, Plaintiff's physician inserted the Implanon® in accordance with Defendants' instructions in Plaintiff's left arm. The insertion was without

complication and Plaintiffs and her physician could palpate the inserted implant after the insertion.

64. Plaintiff thereafter decided to have the Implanon® removed.

65. In July of 2014, Plaintiff's physician was unable to palpate or locate the Implanon® to remove it.

66. Plaintiff underwent unsuccessful attempts, including surgery, to remove the Implanon® during which the implant could not be located.

67. To date, Plaintiff still has the lost Implanon® somewhere in their body. She continues to suffer side effects from the Implanon®.

68. As a result of her lost, irretrievable and irreversible implant, Plaintiff is at risk for serious and even potentially deadly adverse events, including but not limited to, ectopic pregnancy, the inability to stop drug-related reactions, additional unwanted side-effects of the medication and neural or vascular damage.

69. At that time of insertion, Plaintiff was unaware of the concealed information concerning the safety and efficacy of Implanon®, including, but not limited to, the risk of spontaneous migration after insertion in accordance with Defendants' instructions, the risk of a lost, irretrievable implant, and Implanon®'s defective nature, and had no way to determine the truth behind Defendants' concealment and omissions.

70. As a result of using Defendants' product Implanon®, Plaintiff suffered serious injuries including, but not limited to, spontaneous migration of the implant beyond the implant site, inability to locate the implant, inability to remove the implant, unsuccessful, and invasive attempts at implant removal. She also suffers the threat of future infertility,

ectopic pregnancy, the inability to stop a drug-related adverse event and neural and vascular damage.

**FACTS REGARDING PLAINTIFF RUBY GINNS**

71. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if

72. Plaintiff Ruby Ginns was prescribed Implanon® by her health care provider.

73. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants as described herein to purchase Implanon® to her detriment.

74. On November 30, 2012, Plaintiff's physician inserted the Implanon® in accordance with Defendants' instructions in Plaintiff's left arm. The insertion was without complication and Plaintiff and her physician could palpate the inserted implant after the insertion.

75. Plaintiff thereafter decided to have the Implanon® removed.

76. In May of 2013, Plaintiff's physician was unable to palpate or locate the Implanon® to remove it.

77. Plaintiff underwent unsuccessful attempts, including surgery, to remove the Implanon® during which the implant could not be located, as well as surgical complications.

78. To date, Plaintiff still has the lost Implanon® somewhere in their body. She continues to suffer side effects from the Implanon®.

79. As a result of her lost, irretrievable and irreversible implant, Plaintiff is at risk for serious and even potentially deadly adverse events, including but not limited to, ectopic

pregnancy, the inability to stop drug-related reactions, additional unwanted side-effects of the medication and neural or vascular damage.

80. At that time of insertion, Plaintiff was unaware of the concealed information concerning the safety and efficacy of Implanon®, including, but not limited to, the risk of spontaneous migration after insertion in accordance with Defendants' instructions, the risk of a lost, irretrievable implant, and Implanon®'s defective nature, and had no way to determine the truth behind Defendants' concealment and omissions.

81. As a result of using Defendants' product Implanon®, Plaintiff suffered serious injuries including, but not limited to, spontaneous migration of the implant beyond the implant site, inability to locate the implant, inability to remove the implant, and unsuccessful, invasive attempts at implant removal. She also suffers the threat of future infertility, ectopic pregnancy, the inability to stop a drug-related adverse event and neural and vascular damage.

**FACTS REGARDING PLAINTIFF JENNI AKINS**

82. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

83. Plaintiff Jenni Akins was prescribed Implanon® by her health care provider.

84. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants as described herein to purchase Implanon® to her detriment.

85. On February 7, 2012, Plaintiff's physician inserted the Implanon® in accordance with Defendants' instructions in Plaintiff's left arm. The insertion was without

complication and Plaintiff and her physician could palpate the inserted implant after the insertion.

86. Plaintiff thereafter decided to have the Implanon® removed.

87. In October of 2014, Plaintiff's physician was unable to palpate or locate the Implanon® to remove it.

88. Plaintiff underwent unsuccessful attempts to remove the Implanon® during which the Implanon® could not be located.

89. To date, Plaintiff still has the lost Implanon® somewhere in their body. She continues to suffer side effects from the Implanon®.

90. As a result of her lost, irretrievable and irreversible implant, Plaintiff is at risk for serious and even potentially deadly adverse events, including but not limited to, ectopic pregnancy, the inability to stop drug-related reactions, additional unwanted side-effects of the medication and neural or vascular damage.

91. At that time of insertion, Plaintiff was unaware of the concealed information concerning the safety and efficacy of Implanon®, including, but not limited to, the risk of spontaneous migration after insertion in accordance with Defendants' instructions, the risk of a lost, irretrievable implant, and Implanon®'s defective nature, and had no way to determine the truth behind Defendants' concealment and omissions.

92. As a result of using Defendants' product Implanon®, Plaintiff suffered serious injuries including, but not limited to, spontaneous migration of the implant beyond the implant site, inability to locate the implant, inability to remove the implant, and unsuccessful, invasive attempts at implant removal. She also suffers the threat of future

infertility, ectopic pregnancy, the inability to stop a drug-related adverse event and neural and vascular damage.

## CAUSES OF ACTION

### COUNTS I-V
(Pursuant to O.R.C. §2307.01 et seq., I.C. § 34-20-1- et seq., and Common Law)
**DEFECTIVE MANUFACTURING/CONSTRUCTION**
**DEFECTIVE DESIGN/FORMULATION**
**DEFECTIVE WARNING/INSTRUCTION**
**DEFECTIVE DUE TO NONCONFORMITY WITH REPRESENTATION**
**STRICT LIABILITY**

93. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

94. At all times relevant to this action, Defendants were the manufacturers and/or distributors, that designed, produced, created, made, constructed, and/or assembled the Implanon® that was placed into the stream of commerce.

95. The Implanon® expected to and did reach the ultimate users, including Plaintiffs, without substantial change in condition.

96. In their design, manufacture, labeling, warning, instruction, training, sale, marketing and distribution of Implanon®, Defendants:

a. failed to manufacture the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

b. failed to use reasonable care in the testing of the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

c. failed to use reasonable care in the inspection of the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

d. failed to design the Product so as to avoid an unreasonable risk of harm to users in whom the product was implanted, including Plaintiffs;

e. failed to use reasonable care in training their employees, sales representatives and health care providers as to the use of the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

f. failed to use reasonable care in instructing and/or warning health care providers, the FDA and the public of the risk associated with the product, including the risk of spontaneous migration after insertion in accordance with Defendants' instructions and that Implanon®'s non-radiopaque design may entirely prevent imaging technologies from locating a lost Implanon®, so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

g. failed to conform with Defendants' own representations so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

h. failed to use reasonable care in marketing and promoting the product, so as to avoid unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

i. failed to conduct post-market vigilance or surveillance;

j. failed to comply with manufacture requirements of the Medical Device Reporting (MDR) Regulations, including by failing to report and thoroughly investigate reports of serious adverse events;

k. falsely represented and promoted Implanon® was a safe and effective contraceptive option;

l. represented and marketed Implanon® directly to consumers as "reversible" and able to be removed whenever the patient "change[s] [her] mind" when these representations by Defendants were in fact false, misleading, and inaccurate;

m. concealed from Plaintiffs and their health care providers information about the propensity of Implanon® to cause great harm, and/or,

n. otherwise negligently or carelessly designed, manufactured, marketed, distributed, warned, labeled, tested or sold the product.

97. The Implanon,® including its applicator, which was manufactured, designed, sold, distributed, supplied, promoted and/or placed in the stream of commerce by Defendants was defective in its:

a. Manufacture and construction;

b. Design;

c. Inadequate warning or instruction, and/or

d. Failure to conform, when it left the control of Defendants, to their representations.

98. Defendants' Implanon® was defective in that at the time Implanon® left the control of Defendants, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

99. Implanon® was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiffs.

100. At all times herein mentioned, Implanon® was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said Implanon® was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.

101. The nature and magnitude of the risk of harm associated with the design and formulation of Implanon® is high in light of the intended and reasonably foreseeable use of Implanon® as a "reversible" form of contraceptive.

102. Implanon® users would be unaware of the risks associated with Implanon® through either warnings, general knowledge or otherwise. Plaintiffs were not aware of said risks.

103. The design or formulation of Implanon® is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner as a "reversible" form of contraceptive. It was more dangerous than Plaintiffs expected.

104. The intended or actual utility of Implanon® is not of such benefit to justify the risks described herein, including the risk that Implanon® may spontaneously migrate after insertion in accordance with Defendants' instructions and become lost in the body without the ability to retrieve through standard imaging technologies.

105. There was both technical and economic feasibility, at the time Implanon® left Defendants' control, of using an alternative design or formulation that would not cause the risks described herein.

106. A practical and technically feasible alternative design or formulation was available and known by Defendants that would have prevented the harm for which Plaintiffs suffered.

107. Defendant had a duty to warn Plaintiffs and their physician of Implanon®'s defective nature, as well as the risks associated with Implanon®, including the risk of spontaneous migration after insertion in accordance with Defendants' instructions and that Implanon®'s non-radiopaque design may entirely prevent imaging technologies from locating a lost Implanon®.

108. Defendants knew, or in the exercise or reasonable care, should have known about the risks associated with Implanon® as described herein.

109. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning these risks.

110. Defendants' Implanon® is defective due to inadequate post-marketing warning or instruction.

111. Defendants knew, or in the exercise or reasonable care, should have known about the risks described herein, including the risk that Implanon® may spontaneously migrate after insertion in accordance with Defendants' instructions and become lost in the body without the ability to retrieve through standard imaging technologies.

112. Defendants failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning said risks, for which Plaintiffs suffered.

113. The risks described herein are not open and obvious risks or risks that are a matter of common knowledge in regards to Implanon®.

114. The Defendants' product was defective in that, when it left the control of Defendant, the product did not conform to representations made by Defendant.

115. Defendants falsely represented to Plaintiffs that Implanon® was a safe and effective contraceptive option. Defendants also represented and marketed Implanon® directly to consumers as "reversible" and able to be removed whenever the patient "change[s] [her] mind." The representations by Defendants were in fact false, misleading, and inaccurate, as Implanon® is not safe and is dangerous to the health of its users.

116. Instead, at all times relevant herein, Defendants knew Implanon® was defective and had the propensity to spontaneously migrate after insertion in accordance with Defendants' instructions and become lost in the body without the ability to retrieve through standard imaging technologies.

117. At the time the aforesaid representations were made, Defendants concealed from Plaintiffs and their health care providers information about the propensity of Implanon® to cause great harm. Defendants' claims regarding the safety and efficacy of Implanon®

failed to provide an accurate and/or adequate warning of Implanon®'s risks to the Plaintiffs and their healthcare providers despite Defendants awareness of these risks.

118. While Plaintiffs believe and aver that Defendants acted negligently and recklessly in making the representations, in the event Defendants is not found to have acted negligently or recklessly, Defendant is still liable for the damages and injuries suffered by Plaintiffs pursuant to Ohio Revised Code § 2307.01 et seq., Indiana Code § 34-20-1 et seq, and common law.

119. By reason of the foregoing, the Defendant is liable to the Plaintiffs for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in that it did not conform; at the time it left the control of Defendants, to representations made by Defendants.

120. As a direct and proximate result of Defendants' violations of the Ohio Products Liability Act, Indiana Products Liability Act and the common law in their manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective and failing to adequately warn Plaintiffs of the true risks associated with Implanon® use, Plaintiffs suffered physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses.

121. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

**COUNT VI: NEGLIGENCE**

122. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

123. Defendants owed Plaintiffs and all consumers a duty of reasonable care in how it manufactured, designed, sold, distributed, supplied, promoted, placed in the stream of commerce and/or warned of the dangers of Implanon®.

124. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing and distribution of Implanon® in one or more of the following respects:

a. failing to manufacture the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

b. failing to use reasonable care in the testing of the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

c. failing to use reasonable care in the inspection of the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

d. failing to design the Product so as to avoid an unreasonable risk of harm to users in whom the product was implanted, including Plaintiffs;

e. failing to use reasonable care in training its employees, sales representatives and health care providers as to the use of the product so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

f. failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public of the risk associated with the product, including the risk of spontaneous migration after insertion in accordance with Defendants' instructions and that Implanon®'s non-radiopaque design may entirely prevent imaging technologies from locating a lost Implanon®, so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

g. failing to conform with Defendants' own representations so as to avoid an unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

h. failing to use reasonable care in marketing and promoting the product, so as to avoid unreasonable risk of harm to patients in whom the product was implanted, including Plaintiffs;

i. failing to conduct post-market vigilance or surveillance;

j. failing to comply with manufacture requirements of the Medical Device Reporting (MDR) Regulations, including by failing to report and thoroughly investigate reports of serious adverse events;

k. falsely representing and promoting Implanon® was a safe and effective contraceptive option;

l. representing and marketing Implanon® directly to consumers as "reversible" and able to be removed whenever the patient "change[s] [her] mind" when these representations by Defendants were in fact false, misleading, and inaccurate;

m. concealing from Plaintiffs and their health care providers information about the propensity of Implanon® to cause great harm, and/or,

n. otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling, testing or selling the product.

125. As a direct and proximate result of Defendants' negligence, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

126. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to recover punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

## COUNT VII: FRAUD BY CONCEALMENT

127. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

128. Throughout the relevant time period, Defendants knew that Implanon® was defective and unreasonably unsafe for its intended purpose.

129. Defendants had a duty to disclose certain concealed facts, which include the true risks and dangers posed by Implanon® as described throughout the Complaint, particularly as:

a. Defendants were in a superior position to know the true quality, safety and efficacy of Defendants' Implanon®;

b. Defendants knowingly made false claims about the safety and quality of the Defendants' Implanon® in documents and marketing materials Defendants provided to the FDA, physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of Defendants' Implanon® from Plaintiffs.

130. Defendants cemented their duty to provide Plaintiffs with disclosures by choosing to disclose certain limited contraindications while concealing the other grave dangers that form the basis of this suit. This partial disclosure created a duty to fully disclose all Implanon®'s dangers to avoid misleading Plaintiffs and the public.

131. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiffs, their physicians and the medical community that Implanon® was defective, unsafe and unfit for the purposes intended, and that it was not of merchantable quality.

132. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Implanon®.

133. Defendants intentionally concealed and/or failed to disclose the true and defective nature of Implanon® so that Plaintiffs would request and purchase Defendants' Implanon®, and that their healthcare providers would prescribe and recommend Implanon®, and Plaintiffs justifiably acted or relied upon, to their detriment, the concealed and/or non-disclosed facts as evidenced by their purchase of Implanon®.

134. Defendants, by concealment or other action, intentionally prevented Plaintiffs and Plaintiffs' physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of Implanon®.

135. Had Plaintiffs known of Implanon®'s defects, including its risk of becoming irretrievably lost in their bodies, they would not have allowed the devices to be implanted in their bodies.

136. As a direct and proximate result of Defendants' wrongful actions, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

137. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

## COUNT VIII: FRAUDULENT MISREPRESENTATION

138. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege on information and belief as follows.

139. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Implanon®, owed a duty not to deceive the Plaintiffs, their health care providers and the public regarding the character, safety, quality and/or effectiveness of their product.

140. The duty not to deceive is distinct from than the duty to warn and thus, was not abrogated by the Ohio Product Liability Act found at Ohio Revised Code § 2307.71 *et seq*.

141. Defendants fraudulently misrepresented and published information in various forms of media (including, but not limited to, ad campaigns, television, internet, etc.) regarding their product's character, safety, quality, effectiveness and its "reversible" nature.

142. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Implanon®.

143. Defendants utilized direct-to-consumer advertising to market, promote, and advertise Defendants' Implanon®.

144. At the time of Defendants' fraudulent misrepresentations, Plaintiffs were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

145. Defendants breached their duties to Plaintiffs by providing false, incomplete, and misleading information regarding Implanon®.

146. Defendants acted with deliberate intent to deceive and mislead Plaintiffs, their medical providers, and the public.

147. Plaintiffs reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

148. Had Plaintiffs known of Implanon®'s defects, including its risk of becoming irretrievably lost in their bodies, they would not have allowed the devices to be implanted in their bodies.

149. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

150. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

## COUNT IX: BREACH OF EXPRESS WARRANTY

151. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

152. Defendants created express warranties in their selling, distribution, supply, promotion and marketing of Implanon®.

153. These include, but are not limited to, warranties that:

a. Implanon® was a safe and effective contraceptive option;

b. Implanon® was a "reversible" option; and

c. Implanon® was able to be removed whenever the patient "change[s] [her] mind."

154. At the time of making such express warranties, Defendants knew or should have known that Defendants' Implanon® did not confirm to these express representations and that Implanon® was not of merchantable quality, safe or fit for its intended use.

155. Plaintiffs relied on these warranties when choosing to have Implanon® implanted and would not have done so if they knew the representations were false.

156. Defendants breached each of these warranties to Plaintiffs in that Defendants' Implanon® was not of merchantable quality, safe and fit for its intended use.

157. As a direct and proximate result of Defendants' breached warranties, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

158. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

## COUNT X: BREACH OF IMPLIED WARRANTY

159. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

160. By introducing Implanon® into the stream of commerce and promoting its use, Defendants impliedly warranted the product was merchantable, including: that Implanon® would be of average quality; that it would be fit for its ordinary purpose and use; that it would be packaged and labeled properly; and that it would conform to the promises made in the marketing, packaging, and labeling of the product.

161. Implanon® is dangerous as alleged herein, is less effective than promised, is not of average quality, is not fit for its ordinary purpose and use, was not labeled in a way to warn Plaintiffs of its grave dangers, and did not conform to is marketing, packaging, and labeling promises of being safe for use in a human body and reversible.

162. At the time they distributed Implanon®, Defendants knew or should have known that Implanon® was not merchantable.

163. Plaintiffs relied on Defendants' warranties when deciding to allow Implanon® units to be implanted in their bodies. They would not have allowed Implanon® to be implanted if they knew the product was not merchantable and was defective as described herein.

164. As a direct and proximate result of Defendants' breached warranties, Plaintiffs have been injured, sustained pain, suffering, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to, medical expenses.

165. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and

exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

**COUNT XI: INFLICTION OF EMOTIONAL DISTRESS**

166. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

167. Defendants acted in an extreme and outrageous manner in a variety of ways, including by concealing, ignoring and misleading Plaintiffs and the public about Implanon®'s risks.

168. Defendants should have known and/or did know that their conduct could cause and would cause emotional distress Plaintiffs and their families.

169. Implanon® caused Plaintiffs to suffer physical pain and mental anguish, diminished enjoyment of life, medical, health, and incidental and related expenses. These conditions, directly and indirectly caused emotional distress in Plaintiffs.

170. Defendants intentionally caused, or recklessly disregarded the risks of causing this emotional distress.

171. Alternatively, Defendants were negligent in causing Plaintiffs' emotional distress.

172. As a direct and proximate result of Defendants' wrongful actions, Plaintiffs suffer from emotional distress.

173. Defendants' conduct was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety to patients/consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

**COUNTS XII- XIII: LOSS OF CONSORTIUM AND CLAIM FOR MEDICAL EXPENSES**

(AS TO PLAINTIFF MAJOR AKINS AND PLAINTIFFS ROBERT AND JULIE REYNOLDS)

174. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

175. As a result of the foregoing acts and omissions, and the resulting injuries, including, but not limited to, personal injuries, medical expenses, and pain and suffering sustained by Plaintiff Jenni Akins, Plaintiff Major Akins has suffered the loss of companionship, society, services, and consortium of his wife.

176. As a result of the foregoing acts and omissions, and the resulting injuries, including, but not limited to, personal injuries, medical expenses and pain and suffering sustained by Plaintiff Brook Reynolds, Plaintiffs Robert and Julie Reynolds have suffered the loss of companionship, society, services and consortium of their daughter and have also incurred medical expenses on her behalf.

**COUNT XIV: PUNITIVE DAMAGES**

177. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

178. Plaintiffs' injuries were the result of misconduct of Defendants that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.

179. Defendants fraudulently withheld information known to be material and relevant to the harm that the Plaintiffs suffered or misrepresented the information of that type.

180. Defendants engaged in fraudulent and malicious conduct towards Plaintiffs, their medical providers and the public, and thereby acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiffs and the public.

181. By the foregoing, the Defendants are liable to the Plaintiffs for punitive damages, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a defective product.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs each pray for judgment against the Defendants, jointly and severally, as follows:

A. For an award of compensatory damages, including damages against Defendants and each of them for pain and suffering, medical and hospital expenses, loss of income, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants and each of them in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: March 2, 2015

Respectfully Submitted,

/s/Pamela A. Borgess
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**JURY DEMAND**

Plaintiffs hereby demand a trial by jury on all triable issues.

/s/Pamela A. Borgess
Pamela A. Borgess (0072789)